

Glover Dentistry

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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20057

August 19, 2002

Reference docket #01N-0067

Dear Sir or Madam:

I am writing as a practicing dentist with a concern on FDA's proposed rules on dental amalgam products and draft guidance document entitled, "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA.

I have been placing amalgam restorations for 34 years and I have never seen any untoward results from these restorations. I have also removed amalgam restorations for patients undergoing alternative medical treatments and have yet to see a positive result form alloy removal.

I support the FDA's proposal to issue a separate classification for encapsulated amalgam alloy and dental mercury as a class II device with special controls; amend the existing classification for amalgam alloy, a class II preamendments device, by adding special controls; and reclassify from class I with special controls, dental mercury

I wholeheartedly support the comments recently submitted by the American Dental Association. I also strongly support that these proposed rules should preempt state laws that conflict with the requirements encompassed by the proposed rule.

I thank you for your time and considerations on these proposals.

OIN-0067

Joel F. Glover, D.D.S.

Sincerely yours.

Past President, American Association of Dental Examiners, Past Chairman, Council On Dental Education-Commission on

Accreditation



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